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Abstract:

In aspiring to become a true engineering discipline for the biological sciences, the field of synthetic biology has a unique opportunity to create and encourage the widespread adoption of standards to enhance innovation and social impact in the field. This article presents a study of the standards setting efforts by the institutions, firms, governments, and individuals within the field of synthetic biology.

Numerous standards have been proposed in synthetic biology, including those relevant to structure, function, description, measurement, data, information exchange, software, biosafety and biosecurity, and even law. At the present time, the adoption of technical standards has been relatively modest and no one technical standard appears to have dominated the field. Standards covering policies in biosecurity, by comparison, are more firmly established and biosecurity practices governing commercial orders for synthetic DNA have been widely adopted. Among standards-setting groups within the synthetic biology community, most have expressed a preference that standards remain open and accessible to the community as a whole. Recent developments, including the U.S. Supreme Court's decision in *AMP v. Myriad* and the Leahy-Smith America's Invents Act, could help give greater clarity to the scope of patent rights covering innovations and standards in synthetic biology. Copyright and trademark may provide alternatives mechanisms for conferring rights in synthetic biology inventions, setting and reinforcing standards, or promoting open innovation.

Whether formal policies requiring the disclosure and licensing of property rights covering technical standards could be made mandatory or would ultimately be beneficial to the field of synthetic biology remain open questions. What is certain is that the synthetic biology community is unusually attuned to debates surrounding intellectual property and standards setting, and views its engagement in these debates as vital to ensure the continued success of synthetic biology.